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Docket No.: 62078(51590)
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Gavril W. Pasternak et al.

Application No.: 10/588,679 Confirmation No.: 5097

Filed: May 29, 2007 Art Unit: N/A

For: IDENTIFICATION AND CHARACTERIZATION OF MULTIPLE SPLICE VARIANTS OF THE MU OPIOID RECEPTOR GENE Examiner: Not Yet Assigned

RESPONSE TO RESTRICTION REQUIREMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Claims 1-21 are pending in the instant application and are subject to restriction.

The Office Action, on page 2, requires restriction to one of the following groups under 35 U.S.C. §121 and 372:

Group I, claim(s) 1-20, as drawn to isolated MOR splice variant polypeptide, encoding and fully complementary polynucleotides and methods for screening compounds;

Group II, claims 8-13, as drawn to antisense polynucleotides; and

Group III, claim 21, drawn to a method of regulating morphine analgesia.

Furthermore, the Examiner has required election of one separate, distinct polypeptide (SEQ ID NOs: 50, 52, 54, 56, 58, or 60) and its encoding polynucleotide (SEQ ID NOs: 51, 53, 55, 57, 59, or 61).

Applicants note that the present response is filed concurrently with a preliminary amendment. The present amendment is made to correctly refer to sequence identifiers provided in the Sequence Listing filed on August 8, 2006. Applicants note that prior to the present amendment, the sequence identifiers recited in the claims were reversed with respect to polypeptides and polynucleotides. As shown in the Sequence Listing filed on August 8, 2006, SEQ ID NOs: 50, 52, 54, 56, 58, and 60 are polynucleotide sequences and SEQ ID NOs: 51, 53, 55, 57, 59, and 61 are polypeptide sequences. The claims have been amended to be consistent with the Sequence Listing, and to correctly recite the polypeptide and polynucleotides associated with the sequence identifiers. Support for the amendments is found, for example, in the Applicants' specification at page 15, lines 19-24.

In response to the restriction requirement set forth in the Office Action mailed March 31, 2008, Applicants hereby provisionally elect Group I, claims 1-20, and species SEQ ID NO: 50 and SEQ ID NO: 51, which correspond to the polynucleotide and polypeptide sequence of the Mu Opioid Receptor (MOR) splice variant 1B1. Applicants respectfully traverse the requirements for restriction and election, and submit that the requirement is improper.

The Commissioner may require restriction if two or more independent and distinct inventions are claimed in a single application (37 CFR 1.142(a)). Applicants submit that the subject matter of the various groups represent different embodiments of a single inventive concept for which a single patent should issue. The pending claims represent an intricate web of knowledge, continuity of effort, and consequences of a single invention, which merit examination of all claims in a single application. Therefore, it is improper to require that the subject matter of these groups be prosecuted in separate patent applications.

More particularly, a single, searchable, unifying aspect links all of the claims. This single, searchable, unifying aspect relates to splice variants of the Mu Opioid Receptor. A search and examination with respect to the subject matter of all claims can be made without serious burden. As the M.P.E.P. § 803 states:

> If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the

merits, even though they include claims to independent or distinct inventions.

That is, even if the above-enumerated groups of claims are drawn to distinct inventions, the Examiner must still examine the entire application on the merits because doing so will not result in a serious burden.

Applicants submit that the search and examination of all three groups will have substantial overlap, and no serious burden will result from searching and examining all three groups in the same application. This is especially true given Groups I-III share the same element of being drawn to splice variants of the Mu Opioid Receptor, and given the robust and extensive computerized search engines and databases at the Examiner's disposal.

In support of the unity of invention rejection, the Examiner cites Rossi et al., (FEBS Letters 369: 192-196, 1995; hereinafter "Rossi"). The Examiner states that Rossi teaches the use of MOR-1 antisense nucleic acid molecules to block morphine analgesia in rats (Abstract), and that in view of this teaching, Applicants' claims do not form a single inventive concept over Rossi. Applicants respectfully disagree. Rossi fails to describe any human splice variant of the Mu Opiod Receptor, much less the specific human Mu Opioid Receptor splice variants and antisense molecules recited in Applicants' claims. Moreover, Rossi fails to teach or suggest such human sequences. Accordingly, the unity of invention rejection over Rossi should be withdrawn and the elected claims of Group I be rejoined with those of Groups II and III.

Applicants submit this paper in response to the restriction requirement dated March 31, 2008 in the above-referenced patent application, along with a request for a one-month extension of time and the required fee based on small entity status. Applicants believe that no other fees are required for consideration and entry of this paper. Nevertheless, Applicants

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hereby authorize the Commissioner to charge any required fee/underpayment of a fee or credit any overpayment to Deposit Account No. **04-1105**.

Dated: June 2, 2008

Respectfully submitted,

By _____

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